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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,574	06/11/2001	Francis Sullivan	GFN-5285D3CPACN	4282

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Finnegan Henderson Farabow  
Garrett & Dunner LLP  
Attn: Leslie A. McDonell  
1300 I Street NW  
Washington, DC 20005-3315

EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/878,574

**Applicant(s)**

SULLIVAN ET AL.

**Examiner**

Yong D Pak

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21, 23, 26-29 and 38-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-55 is/are allowed.
- 6) ☒ Claim(s) 21, 23, 26-29 and 38-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed on February 18, 2004, amending claim 21, 23, 26, 39 and 40, canceling claims 9, 22, 24-25 and 30-37 and adding claims 43-55, has been entered.

Claims 21, 23, 26-29, 38-55 are pending.

### ***Response to Arguments***

Applicant's arguments, filed on February 18, 2004, with respect to claims 21, 23 and 26-29 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph have been fully considered and are persuasive. The rejection of claims 21, 23 and 26-29 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph has been withdrawn.

Applicant's arguments filed on February 18, 2004, with respect to claims 21, 23, 26-29 and 38-39 under 35 U.S.C. 112, 1<sup>st</sup> paragraph have been fully considered but they are not persuasive.

Claims 21, 23, 26-29 and 38-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants argue that the specification provides an adequate description of the claimed methods. The examiner disagrees. The claims are drawn to a process of using a genus of modulators/inhibitors of any GDP-mannose-4,6-dehydratase (GM4,6D). The specification only describes a method of treatment using antibodies of the GM4,6D of SEQ ID NO:2 or 3. There is no evidence on the record of the relationship between the structure of a modulator/inhibitor of one species of GM4,6D and a modulator/inhibitor of SEQ ID NO:2 and 3.

Claims 21, 23, 26-29 and 38-39 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject with antibodies against the GM4,6D of SEQ ID NO:2 and 3, does not reasonably provide enablement for treating a subject with any modulators/inhibitors against GM4,6D or antibodies against GM4,6D different from SEQ ID NO:2 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the claimed method does not require undue burden, but testing known and unknown modulators of GM4,6D is routine. The examiner disagrees. The claimed invention requires an undue level of experimentation since the specification does not disclose structural identifying characteristics of the genus of modulators/inhibitors/antibodies. The specification only teaches a method of treatment

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using antibodies of the GM4,6D of SEQ ID NO:2 or 3. An assay for finding a product is not equivalent to a positive recitation of how to make a product.

***Allowable Subject Matter***

Claims 40-55 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600